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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

TUNG, P

ART UNIT

PAPER NUMBER

1652

11

DATE MAILED:

07/20/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.
08/951,188

Applicant(s)

Price

Examiner
Peter Tung

Group Art Unit
1652



☒ Responsive to communication(s) filed on Apr 21, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-32 and 68-109 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-32 and 68-109 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Claims 1-32 and 68-109 are pending.

Claim Objections

2. The numbering of claims is not accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 33-74 been renumbered 68-109.

3. Claim 1 is objected to because of the following informalities: what the term "P-TEFb" stands for should be defined in the claim.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 4, 5, 11, 15, 96, 103, 106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. Claims 1, 102-104 and 108 are indefinite because of the use of the phrase "characterized as." In scientific parlance, characterization implies one or more physical steps or procedures, such as structure determination, elemental analysis or quantitative tests, to identify a product. It appears that the applicant intends more than a mere description, since physical steps are lacking in the claims. As such, the reader may be unsure about the meaning of the wording of the claim and additionally, the scope of the claim is unclear because "characterized as" conveys no degree of openness. These phrases can be replaced by standard transitional words such as "having", "comprising", "wherein", and the like.

7. The term "specifically" in claim 1, 4, 5, 11, 23, 77, 84, 87, 96, 103, 106 is a relative term which renders the claim indefinite. The term "specifically" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Including the specific stringent hybridization conditions from the specification (page 68, lines 24-26) will overcome this rejection.

8. The term "includes" in claims 1, 4-6, 23, 68-75, 77-81, 87-91 and 109 is a relative term which renders the claim indefinite. The term "includes" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For the purposes of this Office action, "includes" is understood to be the same as "comprises." It is noted that the use of "has" and "having" is interpreted as open language equivalent to "comprising."

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9. Claims 15 and 31 are indefinite as they are dependent upon claim 1, which has the DNA segment as encoding a P-TEFb subunit and not two subunits in the coding region of the DNA segment.

10. Claim 24 is indefinite as to where the first and second expression units are located. Changing "comprised on" to "comprised in" would correct the problem.

11. Claim 25 is indefinite as to the first and second expression units each being contained in a distinct vector. Changing "comprised on two distinct vectors" to "each comprised in a separate expression vector" would correct the problem.

12. Claim 27 recites the limitation "a first DNA segment" in line 1. There is insufficient antecedent basis for this limitation in the claim.

13. Claims 105-107 are indefinite as an expression unit comprises more than just a promoter. As claimed, the only component of the vector is the promoter that expresses a coding region.

14. The term "stringent ... conditions" in claims 108 and 109 is a relative term which renders the claim indefinite. The term "stringent ... conditions" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. While exemplary conditions for a hybridization under stringent conditions are disclosed in the specification, various other ways of performing a hybridization under stringent conditions are possible. The results obtained from a hybridization performed using stringent conditions would be dependent upon

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what specific conditions are used in the hybridization. Including the specific stringent hybridization conditions from the specification (page 68, lines 24-26) will overcome this rejection.

15. The term “substantially full length” in claims 108 and 109 is a relative term which renders the claim indefinite. The term “substantially full length” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what would be considered a substantially full length P-TEFb or coding region. Removing “substantially full length” would correct the problem.

16. Applicants argue that the specification defines “substantially full length” as meaning a subunit containing the regions or domains necessary for functional activity.

17. Applicant's arguments filed 4/21/99 have been fully considered but they are not persuasive. As argued by Applicants, a “substantially full length” pTEFb kinase subunit would encompass any size fragment of a full length subunit as long as that fragment has functional activity. The meaning of “substantially full length” is contrary to the usual meaning of that term.

Claim Rejections - 35 USC § 112

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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19. Claims 23-26, 77-99, 101 and 109 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a) a DNA coding region which encodes a p-TEFb kinase subunit and which hybridizes to the nucleotide sequence of SEQ ID NO: 1 or 5 and b) a DNA coding region which encodes a p-TEFb large subunit and which hybridizes to the nucleotide sequence of SEQ ID NO: 3, 43 or 48, does not reasonably provide enablement for a coding region that hybridizes to either SEQ ID NO: 1, 3, 5, 43, or 48. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the predictability or unpredictability of the art, and (5) the breadth of the claims. The breadth of the claims encompass any DNA which hybridizes to the DNA of SEQ ID NO: 1, 3, 5, 43, or 48. As there is unpredictability in determining what proteins, if any, are encoded by the large amount of DNAs that are able to specifically hybridize to said DNAs, a large amount of experimentation would be required to determine those DNAs which hybridize and what proteins they would encode. The specification does not provide any other DNAs which would hybridize to said DNAs and insufficient guidance is provided on determining the function of such DNAs.

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20. Claims 1, 4-6, 11, 15-32, 68-75, 77-101, 108 and 109 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Adequate description for the species encompassed by the claim would have relevant identifying characteristics which include 1) structure, 2) physical and/or chemical characteristics, 3) functional characteristics when coupled with a known or disclosed correlation between function and structure, 4) a combination of these. The instant claims are drawn to DNAs encoding a p-TEFb subunit comprising at least 7 to 200 amino acids of specified amino acid sequences. Adequate description of a p-TEFb subunit comprising at least 7 to 200 amino acids requires sufficient description that a person of skill in the art would understand what applicant is claiming. As the p-TEFb subunits range in size from 400 to over 1000 amino acids in length, providing only 7 to 200 amino acids of a p-TEFb would not provide sufficient structure to describe the protein. The claim does not provide physical and/or chemical characteristics of p-TEFb subunits. No functional characteristics of p-TEFb are provided that are linked with a correlation with the subunit function and structure. Additionally, no combination of these identifying characteristics is provided for p-TEFb. Therefore DNAs encoding a p-TEFb subunit comprising at least 7 to 200 amino acids of the specified amino acid sequences are inadequately described.

21. Claims 1, 4-6, 11, 15-32, 68-75, 77-101, 108 and 109 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA encoding a P-TEFb

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subunit comprising specifically defined sequences, does not reasonably provide enablement for a DNA encoding a P-TEFb subunit comprising a contiguous sequence of at least 7 to 200 amino acids of the specified sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The breadth of the claim encompasses any naturally occurring or engineered P-TEFb subunit that comprises at least 7 to 200 contiguous amino acids of the listed SEQ ID NOs. No guidance is provided on how to obtain or identify a P-TEFb based only upon at least 7 to 200 contiguous amino acids. No guidance is provided on which amino acid residues are enzymatically important in the large subunit of P-TEFb. Such guidance is necessary in order to make and use a P-TEFb which comprises only 7 to 200 contiguous amino acids of the specified SEQ ID NOs. As no working examples of an enzymatically active large subunit of P-TEFb comprising only 7 to 200 contiguous amino acids of the specified SEQ ID NOs are provided, there is inadequate guidance on P-TEFb comprising at least 7 to 200 original contiguous amino acids of the specified SEQ ID NOs and still having enzymatic activity.

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22. Applicants argue that the fundamental requirement of the instant claims is that the encoded product be a “pTEFb subunit.” The sequence information is not to be interpreted in a vacuum but read in light of the specification such that the claims cannot be interpreted without reference to the requirement that an encoded product be a p-TEFb subunit.

The specification provides detailed guidance on what constitutes a “p-TEFb subunit.” One of ordinary skill in the art would clearly be able to make and use a DNA segment that encodes a p-TEFb subunit without undue experimentation.

Applicants argue that any practical usefulness is sufficient to satisfy the “how to use” requirement of 35 U.S.C. 112, 1st paragraph.

Applicants argue that the specification provides guidance on obtaining active p-TEFb subunits and important regions of the active subunit. Undue experimentation would not be required in testing p-TEFb variants as numerous assays and significant details are provided on the subunits and would only require routine experimentation.

Applicants argue that “no working examples” is a circular argument and that the specification provides 3 further working examples of enzymatically active p-TEFb large subunits besides SEQ ID NO: 4. The breadth of the working examples is commensurate with the scope of the claims.

23. Applicant's arguments filed 4/21/99 have been fully considered but they are not persuasive. While the claims are to be read in light of the specification, claims are to be interpreted broadly such

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that limitations of the specification are read into the claims. As the instant claims are interpreted, a P-TEFb subunit can be a protein ranging in size from 7 to 200 amino acids.

While the specification provides detailed guidance on a P-TEFb subunit, it does not provide sufficient guidance on P-TEFb subunits of 7 to 200 amino acids in size.

The requirement of “how to use” for a P-TEFb subunit is satisfied but it is not satisfied for P-TEFb subunits of 7 to 200 amino acids in size.

Undue experimentation would be required to determine P-TEFb subunits of 7 to 200 amino acids in size.

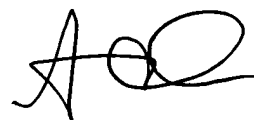
As recited in the previous Office action, “Working examples would provide guidance on where substitutions in the sequences can be made where only 7 contiguous amino acids of SEQ ID NOs: 4, 45, 47 or 50 are present and still have an enzymatically active P-TEFb.” The breadth of the working examples does not provide sufficient enablement for the scope of P-TEFb subunits of 7 to 200 amino acids in size.

Allowable Subject Matter

24. Claims 1-32 and 68-109 and allowable over the prior art of record.
25. No claims are allowed.
26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.



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